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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,277	05/22/2000	Roger K. Cady	57294-012	1639

7590 03/28/2006  
Husch & Eppenger LLC  
401 Main Street  
Suite 1400  
Peoria, IL 61602

EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/575,277	CADY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Vickie Kim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-27,31,32,43,44 and 55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-27 and 55 is/are allowed.
- 6) ☒ Claim(s) 17-19,31,32,43 and 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Status of Application***

1. Acknowledgement is made of amendment 12/6/2005.
2. The claims 17-27, 31-32, 43-44 and 55 are pending and presented for the examination.

### ***Response to Arguments***

3. Applicant's arguments with respect to 112,1st rejection in view of newly amended claims have been fully considered and are persuasive and thus, the 112, 1<sup>st</sup> rejection has been withdrawn.
4. Applicant's arguments filed 12/6/05 have been fully considered but they are not persuasive.

#### 102 rejection (Plachetka, US6,060,499 or US6,586,458)

Applicant's argument (i.e. "aura" is not symptoms but it rather considered as time periods or phase , see remarks at page 12-13) is not persuasive because the alleged statement is self-conflicting with applicant's own admission found in instant specification. At page 2, lines 5, applicant uses the term "aura symptoms" , as well as numerous documents available in the field(see PTO-892). For instance, the dictionary (Webster 1913 or worldnet ) states that "Aura' is a sensation felt before the onset of a convulsion or migraine headache.

Furthermore, applicant admitted , at page 2 line 12-19, that prodrome symptoms may occure in migraine with or without aura(IHS1.1). At same page 2, lines 17-19,

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Applicant also states that HIS prefers the term premonitory symptoms over prodrome due to historical use of prodrome to describe aura and prodrome symptoms as used herein is synonymous to premonitory symptoms. At page 2, lines 5-6, applicant states that aura symptoms includes visual disturbances.

Thus, applicant's argument is not persuasive, rather conflicting with his own statement, when applicant argues that Plachetka's patents fail to anticipate the claims whereas Plachetka anticipates instant claims because it teaches not only aura but also visual disturbances such as "scotoma" and prophylactic migraine relief by administering 5HT when the first onset of the precursor indicia of a migraine headache is appearing, see col. 8. Applicant's argument that Plachetka's patent fails to teach "determining prodromal symptoms of migraine" is not persuasive because the teaching mentioned above naturally include the determining steps of prodromal symptoms such as scotoma or aura. Thus, the claims 17-19, 31-32 and 43-44 are maintained as rejected.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United

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States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 17-19, 31-32 and 43-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Plachetka(US6060499 or 6,586,458).

The claims are drawn to a composition and a preemptive prophylaxis migraine method using an antimigraine composition wherein the composition contains 5HT<sub>1</sub> agonist as active ingredient. Optionally, the preemptive prophylaxis method uses the composition comprising 5HT<sub>1</sub> in combination with NSAID such as COX-2 inhibitor.

Plachetka (US'499 or '458 hereafter) teaches a method of treating migraine using a 5HT<sub>1</sub> agonist such as naratriptan(1-100mg, see column 5) in combination with NSAID(e.g. COX-2 inhibitor), see abstract, claims and col. 7-col.8. US'458 further teaches that the treatment (Plachetka's) provides an initial migraine relief which reduces or abolishes the symptoms from first onset of the precursor indicia of a migraine headache such as the aura and visual "scotoma", see col.8.

It is noted that the aura is a typical prodromal symptom of migraine as evidenced by applicants' own admission, see instant specification page 1, line 30. As clearly evidenced by the teaching of Plachetka's patents, the preemptive prophylaxis migraine method would have been envisaged by the treatment of US'458 which provides the avoidance of migraine by treating precursor symptoms.

Although the terminology used in application and the patent may not be the same, but the function would cover the scope of the claimed invention.

It is well known in the art as evidenced by Levin(US6432986) that teaches the definition of prodromal symptoms of migraine headache including depression, irritability,

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restlessness, anorexia, scintillating scotomas, visual changes, paresthesias and hemiparesis, see col.2, lines 58-64.

Thus, all the critical elements required by the instant claims are taught by the cited reference and the claimed subject matter is not patentably distinct.

***Conclusion***

2. No claim is allowed.
3. As indicated previously, claims 20-27 and 55 are allowed.
4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Conclusion***

1. No claim is allowed.

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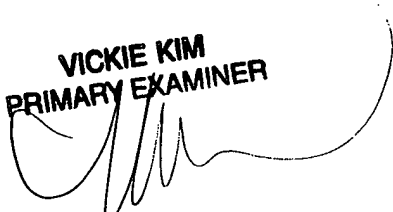
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579.

The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**VICKIE KIM  
PRIMARY EXAMINER**



Vickie Kim  
March 20, 2006  
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